NEBRASKA CATTLEMEN

"Representing the state's largest ag industry"



December 20, 2005

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2002N-0273 "Substances Prohibited From Use in Animal Food or Feed"

On behalf of the Nebraska Cattlemen (NC), I appreciate this opportunity to share with the FDA our perspectives on the proposed rule entitled "Substances Prohibited From Use in Animal Food or Feed." NC will provide comments in two areas of concern in this document.

Nebraska Cattlemen is the largest cattle organization in the state of Nebraska. Nebraska produces over 20% of the U.S. beef supply and is the number one state in live animal and meat exports totaling approximately $1.05 billion annually.

**Disposal of Specified Risk Material (SRM)**

FDA agrees with the affected industry that a comprehensive plan will be needed to safely dispose of the materials covered by the proposed rule. The proposed rule speculates that the amount of material to be disposed of would a "limited amount" due to rule limiting the list of SRMs that would require disposal. The rule states that FDA believes that these materials can be disposed of through incineration, landfills or alkaline digestion.

The rule does not however offer a comprehensive plan, that FDA agrees is needed, in order to comply with this rule. Areas of concern that a comprehensive plan needs to address include but are not limited to:

- Will additional inspectors or inspector time be needed to insure proper disposal of the materials proposed by the rule?
- Are there rules already established by the Environmental Protection Agency (EPA) or state agencies that would make the proposed methods of disposal of the materials difficult or illegal?
- What will be the additional cost to the industry in order to comply with the comprehensive plan once it is established?

NC strongly urges FDA to provide a sound comprehensive plan for the disposal of all ruminant by-products prior to implementing any changes in the proposed rule. Additionally, NC would offer to assist in developing the plan and urges FDA to consider science and risk analysis from industry input for plan development.

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Historic Federal Trust Building • 134 South 13th Street, Suite 900 • Lincoln, NE 68508-1917
(402) 475-2333 • Fax (402) 475-0822 • nc@necattlemen.org • www.nebraskacattlemen.org

**Decreasing BSE risk in the U.S.**

Given the low risk of BSE in the United States, questions are raised regarding the necessity of implementing the proposed rule as written. In fact, while NC supports all reasonable, science and risk analysis based steps to prevent the amplification and spread of BSE, the proposed rule goes well beyond reasonable steps given the apparent real BSE risks in the United States.

The National Cattlemen's Beef Association reports that "since 1990, the U.S. targeted surveillance program has sampled more than 600,000 animals and identified one indigenous case of BSE, a 12 year old cow born, before the 1997 feed ban went in place. Even though the rate of BSE in cattle with central nervous system symptoms has been found to be nearly 1 out of 3 in the EU, the United States tests over 300 such cases for BSE annually and over 4600 since 1990 without finding a single case of BSE. This data provides us confidence that if the disease is present at all, it is at a very low prevalence. This is important as a low BSE prevalence estimate in the United States is one of the critical assumptions within the Harvard Center for Risk Analysis study. The Harvard study predicted that even if BSE had been introduced into the United States the risks were low and that prompt action has already pushed the disease toward eradication." NC agrees with this report.

On August 4, 1997, FDA implemented a final rule, 21 CFR Part 589.2000, that prohibits the use of most mammalian protein in feeds for ruminant animals to prevent the establishment and amplification of BSE through animal feed in the United States,. The enforcement of the rule entails inspections of renderers, feed mills, ruminant feeders, protein blenders, pet food manufacturers, pet food salvagers, animal feed distributors and transporters, ruminant feeders and other entities. The FDA has routinely posted all results in a database accessible via the FDA's website. Since the rule went into effect, it is clear that the animal feed industry has committed to implementing the regulation. The result is BSE amplification risks have continued to be reduced and no evidence exists that the disease prevalence exceeds the range of options evaluated in the Harvard Center for Risk Analysis study. These positive facts affirm the effectiveness of the U.S. system and refute the need for additional BSE prevention measures.

Nebraska Cattlemen has and remains completely dedicated to following a science and risk analysis based program to prevent the introduction, amplification and spread of BSE. However, at this time, over 15 years of action, information and analysis indicate that no data exists to support the FDA altering the existing feed regulations.

Respectfully submitted by:

Pete McClymont
President, Nebraska Cattlemen